

New rules for lung transplants lead to unintended consequences

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Varun Puri, MD, (center) and a surgical team perform a recent lung transplant at Barnes-Jewish Hospital. Associate surgical director of the lung transplant program at Washington University School of Medicine in St. Louis and Barnes-Jewish Hospital, Puri is part of a research team that detailed unintended consequences of a new national policy on allocating donor lungs for transplant patients. Credit: Tim Parker/Washington University School of Medicine

A donated lung suitable for transplant is a scarce resource. For this reason, the national policy determining which patients on the lung transplant waiting list will receive such an organ has provoked significant discussion and recently generated much controversy. At issue is whether lungs should go to the sickest patients within a local area or the sickest patients in a broader region—all while balancing the likelihood of whether a transplant will be successful.

In 2017, in response to a lawsuit filed by a 21-year-old woman on the waiting list for lungs in New York City, a federal court order changed the policy covering the distribution of lungs donated for [transplant](#). Previously, first priority for a [lung transplant](#) was given to the sickest [patients](#) on the waiting list at regional organ procurement organizations. The new policy expands the geographical boundaries, stipulating that the lungs be offered first to a patient within a 250-mile radius of the donor's hospital. Lungs that can't be matched to patients within that initial boundary are then offered to patients within a radius of 575 miles and then to patients across the nation.

However, the policy change has had several unintended consequences, according to a new study from Washington University School of Medicine in St. Louis. The new policy has imposed a significant logistical burden on organ procurement organizations and surgical teams involved in retrieving the donated organs. These teams now are much more likely to have to fly to other organ procurement regions to retrieve lungs for transplants. This has directly translated into a significant increase in the costs associated with organ procurement, the new study found. The added costs are related to longer travel distances that often require air transport, increased medical staffing and the frequent use of expensive equipment to keep lungs viable. The longer travel distances also lengthen the time that lungs are stored in a cold solution, which may contribute to the deterioration of organ quality.

The study is available online in the *American Journal of Transplantation*.

"The new policy represents a dramatic, far-reaching change in the field," said the study's first author, Varun Puri, MD, an associate professor in the Division of Cardiothoracic Surgery and associate surgical director of the [lung](#) transplant program at Washington University and Barnes-Jewish Hospital (BJH). "The concern for busy transplant programs such as ours that serve rural areas is that the new policy will overlook transplant patients in Missouri, Southern Illinois and the Midwestern region in favor of those farther away, in larger cities. The policy has imposed a much greater need to travel outside the St. Louis region to procure lungs for transplant."

The study also examined six months of national data following the policy change. Overall, the number of lung transplants performed nationwide has remained steady after the new policy went into effect, with 1,142 performed in the six months before the new policy went into effect and 1,146 in the six months afterward. It was hoped that the new policy would lower the chances of patients dying on lung transplant waitlists. However, over the six months before the policy change, 169 patients were removed from the waitlist due to death or becoming too sick to undergo transplant surgery, while 190 patients were removed for the same reasons after the policy change.

Patients awaiting lung transplants are scored to determine their health status; a higher score indicates a higher degree of illness. "Although the score of patients undergoing transplant has increased slightly since the policy change, the difference is not meaningful from a clinical standpoint," Puri said. "That puts patients at smaller transplant programs at a disadvantage. It is likely that lungs originating close to smaller transplant centers would be offered first to patients in large metro areas within the 250-mile radius. This policy places smaller programs at a disadvantage, as many may not be able to afford to maintain transplant

programs if lungs from their regions are offered to larger transplant centers in larger metropolitan areas. This raises the problem of access, particularly with a negative impact on patients in economically disadvantaged parts of the country, who cannot travel to distant larger centers for their transplants."

Fragility of lungs makes them susceptible to injuries and infections and, therefore, they are deemed unsuitable for transplant in the majority of potential donors. In the United States, only about 20 percent of lungs meet clinical transplant standards, which is far lower than other organs, such as kidneys or livers.

Nationwide, about 1,500 people are on waiting lists for a lung or a lung-and-heart transplant, according to the United Network for Organ Sharing (UNOS), which manages organ allocation on behalf of the federal government. Altogether, nearly 124,700 are on transplant waiting lists for all organs.

"A similar allocation policy that redistributes donated organs for transplant to larger metropolitan areas has been implemented for hearts, and a new policy for livers is set to take effect April 30," said the study's senior author, Daniel Kreisel, MD, Ph.D., the surgical director of lung transplantation at the School of Medicine and BJH. "We need more national debate about what is fair and equitable, but also taking into account the increasing costs, which can become prohibitive to transplant centers and patients."

The researchers compared data from before and after the new policy went into effect. The data comes from UNOS and the Washington University/BJH lung transplant program, the latter of which has performed about 1,700 lung transplants since 1988 in conjunction with Mid-America Transplant, the organ procurement organization serving the region. The Washington University/BJH lung transplant program is

one of the busiest programs in the United States and, according to a recent report from the Scientific Registry of Transplant Recipients, it has one of the highest one-year survival rates in the country.

The researchers examined deidentified data of 77 patients who received lung transplants from the Washington University/BJH transplant program in 2017 during the 11-month period before the policy change, as well as from 50 patients who underwent the procedure after the policy change, from Nov. 25, 2017, through June 4, 2018. They found the number of lung transplants declined from local donors—from 45 transplants (58 percent) before the policy change, to 15 (30 percent) afterward.

After the policy change, the median cost of retrieving a lung for transplantation via the Washington University/BJH transplant program nearly doubled from \$34,000 per patient to \$70,203. The price includes fees for land or air transportation; travel by a surgeon and others on the transplant team who determine if the lung is suitable for transplantation; and equipment costs to preserve the organ while it is outside of the body. This analysis likely underestimates the increase in cost because a proportion of air flights to retrieve donor lungs turn out to be futile, as the organs are not suitable for transplantation. For example, it costs an additional \$10,000 to \$15,000 for procurement teams to fly a few hundred miles to evaluate a donor lung even if the lung ultimately is deemed unsuitable for transplant.

"If this trend we have observed continues, it will increase the acquisition cost for organs and lead to higher costs for lung transplantation," Kreisel said. "We know of one instance in which a transplant team from St. Louis was flying to Chicago to procure a lung around the same time that a team from Chicago was flying to St. Louis to procure a lung, where the recipients had similar degrees of lung disease. That is a tremendous waste of resources."

Local transplants are also easier and less expensive to coordinate logistically, while retrieving organs at a distant location often requires nighttime flying, which can be more dangerous. "One hundred percent of Barnes-Jewish Hospital's local lung transplants were performed in the daytime as opposed to 67 percent with distant donors, where transplants were performed at night," added Kreisel, who is the G. Alexander Patterson, MD/Mid-America Transplant Endowed Distinguished Chair in Lung Transplantation.

Researchers also analyzed data in a UNOS report released in June 2018. In a six-month period after the new policy took effect, the number of local lung transplants declined nationally by nearly half, from 629 before the [policy change](#) to 356 afterward. Additionally, the new policy required extended use of expensive techniques designed to preserve lung viability, increasing from 42 cases to 119—an increase of 283 percent.

The data represent early trends, the researchers said. More study is needed to determine the long-term effects of changes to the lung allocation [policy](#).

More information: Puri V, Hachem RR, Frye CC, Harrison MS, Semenkovich TR, Lynch JP, Ridolfi G, Rowe C, Meyers BF, Patterson GA, Kozower BD, Pasque MK, Nava RG, Marklin GF, Brockmeier D, Sweet SC, Champman WC, Kreisel D. Unintended Consequences of Changes to Organ Allocation Policy. *American Journal of Transplantation*. Published online Feb. 13, 2019. [dx.doi.org/10.1111/ajt.15307](https://doi.org/10.1111/ajt.15307)

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